

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA**

IRISH 4 REPRODUCTIVE HEALTH
et al.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
et al.,

Defendants.

Case No. 3:18-cv-0491-PPS-JEM

**MEMORANDUM SUPPORTING FEDERAL DEFENDANTS'
MOTION FOR PARTIAL SUMMARY JUDGMENT**

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INTRODUCTION

Earlier this year, in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020), the Supreme Court held that the Affordable Care Act (ACA or Act) authorizes the federal agencies that administer it (the Agencies)¹ to provide exemptions from the Act’s regulatory contraceptive requirements for employers with religious and moral objections. The Court explained that the Agencies’ “broad discretion” and “sweeping authority” under the ACA to define preventive care allowed them to create the religious and moral exemptions. *Id.* at 2380, 2381. The Court also held that “it was appropriate for the [Agencies] to consider” the Religious Freedom Restoration Act (RFRA) in promulgating the exemptions by regulations (the Final Rules), and that, “under RFRA, the [Agencies] must accept the sincerely held complicity-based objections of religious entities.” *Id.* at 2383.

Little Sisters has significant implications here. Federal Defendants have moved to dismiss all but one of the claims in Plaintiffs’ second amended complaint, Fed. Defs.’ Mot. Dismiss, ECF No. 109; 2d Am. Compl., ECF No. 102, and now move for summary judgment on the remaining claim that the Final Rules are arbitrary and capricious under the Administrative Procedure Act (APA). Because *Little Sisters* strongly indicates that the Agencies reasonably exercised their broad discretion in creating the religious and moral exemptions in the Final Rules, Plaintiffs’ remaining claim has no merit.

The Final Rules explained that the exemptions were necessary to alleviate substantial burdens on sincerely-held religious and moral beliefs. Indeed, *Little Sisters* made clear that RFRA required the Agencies to consider the existence of such burdens. Additionally, Plaintiffs lack standing to claim that the Final Rules are overinclusive, a meritless claim in any event because the

¹ The Departments of Health and Human Services, Labor, and Treasury.

Agencies reasonably exercised their sweeping discretion in defining the scope of the exemptions. The Final Rules also considered and responded to significant issues raised in comments, including issues relating to women's health, economic security, and equality. Moreover, contrary to Plaintiffs' assertion, the Agencies did not reverse prior factual findings or abandon prior positions in promulgating the Final Rules; rather, the Agencies simply reached different policy-related conclusions and explained their reasons. Finally, Plaintiffs fail to assert a valid claim regarding the Agencies' regulatory impact analysis, but in any event, the Agencies' analysis is reasonable. The Court should therefore enter summary judgment on Count III of the second amended complaint to the extent that it alleges that the Final Rules are arbitrary and capricious.

BACKGROUND

I. The Affordable Care Act and the Contraceptive-Coverage Mandate

The ACA requires most group health plans and health-insurance issuers offering group or individual health coverage to provide coverage for certain preventive services without "any cost sharing requirements." 42 U.S.C. § 300gg-13(a). Rather than specify which women's preventive care must be covered, the Act requires coverage "with respect to women," of such "additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [(HRSA)]," a component of the Department of Health and Human Services. *Id.* § 300gg-13(a)(4). In August 2011, HRSA issued guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods for women, including oral contraceptives, diaphragms, injections and implants, emergency contraceptive drugs, and intrauterine devices. *See* 77 Fed. Reg. 8725, 8725-26 (Feb. 15, 2012).

At the same time, invoking their authority under 42 U.S.C. § 300gg-13(a)(4), the Agencies promulgated interim final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,621, 46,623 (Aug. 3,

2011); 77 Fed. Reg. at 8725. Rather than provide an exemption for all organizations with religious or moral objections, as various groups urged, 78 Fed. Reg. 8456, 8459-60 (Feb. 6, 2013), the Agencies offered an “accommodation” for religious not-for-profit organizations, 78 Fed. Reg. 39,870, 39,874-82 (July 2, 2013). The accommodation allowed a group health plan established or maintained by an eligible objecting employer, or arranged for students by an eligible organization that is an institution of higher education, to opt out of any requirement to directly “contract, arrange, pay, or refer for contraceptive coverage,” *id.* at 39,874, by providing notice of its objection. The regulations then generally required the employer’s or school’s health insurer (in the case of insured group health plans) or third-party administrator (in the case of self-insured plans) to provide or arrange payments for contraceptives for plan participants. *See id.* at 39,875-80.

The Agencies engaged in nearly “six years of protracted litigation” to defend the mandate and accommodation against challenges brought by both for-profit and non-profit entities with religious or moral objections. *Little Sisters*, 140 S. Ct. at 2373. This litigation led to two rulings from the Supreme Court. In *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), the Court held that the mandate substantially burdened the religious exercise of a for-profit entity, and that the mandate was not the least restrictive means of achieving a compelling governmental interest because, at a minimum, the less-restrictive accommodation made available to non-profit entities could be extended to for-profit entities. In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), the Court vacated rulings from multiple appellate courts regarding the adequacy of the accommodation and instructed the Agencies to investigate whether they could “accommodate[] petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans ‘receive full and equal health coverage, including contraceptive coverage.’” 136 S. Ct. at 1560. In response

to years of litigation and Executive Order 13,798, the Agencies found it “appropriate to reexamine” the mandate’s exemption and accommodation. 82 Fed. Reg. 47,792, 47,799 (Oct. 13, 2017).

II. The Interim Final Rules

In October 2017, the Agencies issued two interim final rules (IFRs) requesting public comments and expanding the exemption while continuing to offer the existing accommodation as an optional alternative. The first IFR expanded the religious exemption to all nongovernmental plan sponsors, as well as to institutions of higher education in their arrangement of student health plans, to the extent that these sponsors and institutions had sincere religious objections to providing contraceptive coverage. *See id.* at 47,806. The Agencies “determined that an expanded exemption, rather than the existing accommodation, [wa]s the most appropriate administrative response to the religious objections raised by certain entities and organizations” because, “[d]espite multiple rounds of rulemaking” and even more litigation, they “ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations” or resolved the pending legal challenges that had divided the courts. *Id.* at 47,799. The second rule created a similar exemption for entities with sincerely held moral objections to providing contraceptive coverage; unlike the religious exemption, this rule did not apply to publicly traded companies. *See* 82 Fed. Reg. 47,838 (Oct. 13, 2017).

The IFRs were challenged in several lawsuits and enjoined by two district courts. *See California v. Health & Human Servs.*, 281 F. Supp. 3d 806, 814 (N.D. Cal. 2017), *aff’d in part, vacated in part, remanded sub nom. California v. Azar*, 911 F.3d 558 (9th Cir. 2018); *Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 563 (E.D. Pa. 2017), *aff’d*, 930 F.3d 543 (3d Cir. 2019), *rev’d*, 140 S. Ct. 2367 (2020).

III. The Final Rules

The Agencies considered more than 110,000 comments received on the IFRs, and on

November 15, 2018, issued final versions of the religious exemption and moral exemption rules. The Agencies made changes in response to the comments, and addressed them in the preambles, but those changes did not alter the fundamental substance of the exemptions set forth in the IFRs.

The final religious exemption “do[es] not remove the contraceptive coverage requirement generally from HRSA’s Guidelines.” 83 Fed. Reg. 57,536, 57,537 (Nov. 15, 2018). What it does do is “finalize exemptions” for “[n]on-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals.” *Id.* “In addition, it maintains the prior “accommodation process,” which an employer who objects to paying for contraceptive coverage directly can use to avoid such direct payments, while still enabling “the persons covered in their plans [to] receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators.” *Id.*

The final moral exemption fulfills the same purpose that it did in its interim form, namely, to “protect sincerely held moral objections of certain entities and individuals.” 83 Fed. Reg. 57,592, 57,592 (Nov. 15, 2018). The Agencies considered, but declined to follow, public comments asking for the moral exemption to be expanded to publicly traded or government entities. *Id.* at 57,616-19. Importantly, like the religious exemption, the moral exemption “do[es] not remove the contraceptive coverage requirement generally from HRSA’s guidelines.” *Id.* at 57,593.

IV. The Supreme Court’s Decision in *Little Sisters*

Before the Final Rules were set to take effect, they were preliminarily enjoined by district courts in the Third and Ninth Circuits, as affirmed on appeal. *See California v. U.S. Dep’t of Health & Human Servs.*, 941 F.3d 410 (9th Cir. 2019); *Pennsylvania v. President of United States*,

930 F.3d 543 (3d Cir. 2019). The Supreme Court granted petitions for a writ of certiorari to the Third Circuit, reversed the court of appeals, and remanded the cases for further proceedings consistent with its opinion. *Little Sisters*, 140 S. Ct. at 2386.

In so doing, the Court addressed three issues that are relevant to this motion. First, the Court recognized the Agencies’ care in responding to comments on the IFRs and the strength of the Agencies’ analysis generally, noting that the Final Rules “responded to post-promulgation comments, explaining their reasons for neither narrowing nor expanding the exemptions beyond what was provided for in the IFRs.” 140 S. Ct. at 2378. The Court also observed that the “final rule creating the religious exemption [] contained a lengthy analysis of the Departments’ changed position regarding whether the self-certification process violated RFRA” and explained that “in the wake of the numerous lawsuits challenging the self-certification accommodation and the failed attempt to identify alternative accommodations after the 2016 request for information, ‘an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified’” in *Hobby Lobby*. *Id.* (quoting 83 Fed. Reg. at 57,544-45).

Second, the Court emphasized the “extraordinarily broad general directive” that 42 U.S.C. § 300gg-13(a)(4) gave HRSA to define preventive care and screenings and to create the religious and moral exemptions. 140 S. Ct. at 2381-82 (internal quotation marks and alterations omitted). Hence, “HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings,” and “to identify and create exemptions from its own Guidelines.” *Id.* at 2380.

Third, the Court rejected Pennsylvania’s argument that the Agencies “could not even consider RFRA as they formulated the religious exemptions.” *Id.* at 2382-83. To the contrary, the Court held that, given “the potential for conflict between the contraceptive mandate and RFRA” and the Court’s prior opinions, it was “appropriate for the [Agencies] to consider RFRA” and

“unsurprising that RFRA would feature prominently in the [Agencies’] discussion of exemptions.” *Id.* at 2383. Indeed, the Court observed that, had the Agencies not considered RFRA, they “would certainly be susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem.” *Id.* at 2384.²

V. The Present Case

In June 2018, Plaintiffs—a student association and individuals who use Notre Dame’s faculty or student health plans—filed this lawsuit against the Agencies, their Secretaries (in their official capacities), and the University. Both the Agencies and Notre Dame moved to dismiss. Before the parties completed briefing, the Agencies issued the Final Rules. Plaintiffs subsequently amended their complaint, and Defendants renewed their motions to dismiss. The Court partially granted these motions in an order filed January 16, 2020. *Irish 4 Reproductive Health*, 434 F. Supp. 3d. 683 (N.D. Ind. 2020). Shortly thereafter, the Supreme Court granted certiorari in *Little Sisters*, and this Court stayed further proceedings pending the outcome of that case.

In light of the Supreme Court’s decision, Plaintiffs filed a second amended complaint on August 20, 2020. Federal Defendants have moved to dismiss Courts I, II, and IV of the second amended complaint in their entirety and Count III to the extent that it alleges violations of the Establishment Clause. *See* Fed. Defs.’ Mot. Dismiss 2d Am. Compl., ECF No. 109. Federal Defendants now move for summary judgment on the remainder of Count III of the Second Amended Complaint, which alleges that the Final Rules are arbitrary and capricious.

ARGUMENT

Plaintiffs allege that the Rules are arbitrary and capricious under the APA for almost a dozen reasons, but none is persuasive. As *Little Sisters* makes clear, the Agencies’ explanation of

² The Court also held that the Third Circuit had erred in concluding that the Final Rules were procedurally improper. *Little Sisters*, 140 S. Ct. at 2384-86.

the Final Rules was thorough and rational, appropriately considered the need for exemptions under RFRA, and offered a “lengthy analysis of the [Agencies’] changed position regarding whether the self-certification process violated RFRA.” *Little Sisters*, 140 S. Ct. at 2378. These statements directly contradict this Court’s prior assertions that the Final Rules “offered little explanation” and failed to “provide meaningful analysis” for the Agencies’ decision to create the exemptions. *Irish 4 Reprod. Health*, 434 F. Supp. 3d at 704. This Court should therefore revisit its conclusion that “Plaintiffs have stated a plausible claim” that the Rules are arbitrary and capricious, *id.*, and grant summary judgment to Federal Defendants.

The Final Rules easily satisfy the arbitrary-and-capricious standard. “The scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see* 5 U.S.C. § 706(2)(A). “[A]n agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.* With respect to a change in policy, an agency need not demonstrate “that the reasons for the new policy are better than the reasons for the old one,” but only that “the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better.” *FCC v. Fox Tele. Stations, Inc.*, 556 U.S. 502, 515 (2009). In situations where the “prior policy has engendered serious reliance interests that must be taken into account,” or an agency has reached different factual conclusions, an agency need only provide a “reasoned explanation” for treating differently “facts and circumstances that underlay or were engendered by the prior policy.” *Id.* at 515-16.

Plaintiffs cannot show the Rules are arbitrary and capricious under these standards.

Accordingly, the Court should enter judgment in favor of Federal Defendants on Plaintiffs’ “arbitrary and capricious” claims in Count III.

A. The Agencies Offered an Adequate Justification for the Rules.

Plaintiffs first assert vaguely that the agencies failed to “offer adequate justification for the Rules,” 2d Am. Compl. ¶ 182(a). This claim lacks merit. The Final Rules contain voluminous explanations of the Agencies’ previous position, their current position, the Agencies’ recognition that their position had changed, discussions of both sides of the issue from public comments, and extensive reasoning for their conclusions in the Final Rules. *See, e.g.*, 83 Fed. Reg. 57,546-56.

In short, the Agencies demonstrated why, in their judgment, the policy interests in favor of expanding the exemptions outweigh the interests in leaving the contraceptive-coverage mandate unchanged: the evidence on the benefits of the contraceptive-coverage mandate is more mixed—and the religious and conscience objections to complying with the mandate more substantial—than the Agencies previously acknowledged. 83 Fed. Reg. at 57,555-56. *See Nat’l Ass’n of Home Builders v. EPA*, 682 F.3d 1032, 1038 (D.C. Cir. 2012) (noting that a “[policy] reevaluation is well within an agency’s discretion,” even without new facts); *see also Organized Vill. of Kake v. Dep’t of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015).

B. The Rules Are Appropriately Tailored.

Plaintiffs allege that the Rules are arbitrary and capricious because their exemptions were not “tailor[ed] . . . to apply only when necessary to alleviate a substantial burden on religious exercise[.]” 2d Am. Compl. ¶ 182. To start, this argument is clearly wrong as to the Moral Exemption Rule, which was not designed to alleviate “a substantial burden on religious exercise,” but to provide relief to those with a non-religious, moral objection to using the accommodation. *See, e.g.*, 83 Fed. at 57,593. The Moral Exemption Rule cannot be faulted for failing to do something that it was not intended (and does not purport) to do. Moreover, Plaintiffs have no

standing to challenge the Moral Exemption Rule because Notre Dame has not invoked it and Plaintiffs have thus suffered no injury in fact traceable to the rule. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992).

Plaintiffs' tailoring allegation fares no better as to the Religious Exemption Rule. The allegation presumably subsumes two separate arguments. The first is that the religious exemption is arbitrary and capricious because an entity without a religious objection to the use of the accommodation can invoke it. *See Little Sisters*, 140 S. Ct. at 2398 (Kagan, J., concurring in the judgment). The second is that the religious exemption applies to publicly traded companies, which seem unlikely to harbor religious objections. *See id.* at 2399; 83 Fed. Reg. at 57,562-63.

As a threshold matter, Plaintiffs lack standing to raise these allegations. Even if an entity without an objection to the accommodation can invoke the Religious Exemption Rule, Notre Dame is not such an entity. It objects to the accommodation on religious grounds. *See* Letter on Health Care Coverage from University President Fr. John Jenkins, C.S.C., Feb, 7, 2018, <https://president.nd.edu/homilies-writings-addresses/letter-on-health-care-coverage/>. Notre Dame also is not a publicly traded company. IRS Determination Letter, April 30, 2019.³ Plaintiffs, then, are seeking to vindicate the rights of third parties—*i.e.*, those affiliated with schools that have no religious objection to the accommodation, or those who work for employers that have no religious objections to the accommodation, or are publicly traded companies. They cannot do so. *See Kowalski v. Tesmer*, 543 U.S. 125, 128-129 (2004). The law presumes that those third parties would do a better job, if and when the time comes, of securing any rights they have. *Id.* at 129.

In any case, even if Plaintiffs had standing, neither of their likely arguments demonstrates that the Religious Exemption Rule is arbitrary and capricious. To begin with, “[t]he APA does

³ https://controller.nd.edu/assets/309030/und_federal_determination_letter_dated_02.28.2018.pdf.

not . . . require agencies to tailor their regulations as narrowly as possible to the specific concerns that generated them.” *Associated Dog Clubs of New York State, Inc. v. Vilsack*, 75 F. Supp. 3d 83, 92 (D.D.C. 2014). Rather, “[a]n agency has wide discretion in making line-drawing decisions” and “is not required to identify the optimal threshold with pinpoint precision.” *Nat’l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214-15 (D.C. Cir. 2013) (quotation marks omitted). The line drawn need only be “within a zone of reasonableness.” *Id.* (quotation marks omitted).

The Religious Exemption Rule easily satisfies this standard. The rule is intended to alleviate the burden on those whose religious objections to the mandate are not adequately addressed by the accommodation, which it does by exempting such entities from the mandate entirely. *See* 83 Fed. Reg. at 57,556. That others whose objections to the mandate *could* be addressed by the accommodation might be able to invoke the exemption does not render the rule unreasonable, and to hold otherwise would be to demand the pinpoint precision the APA does not require. Furthermore, there is no reason to think that, in practice, the exemption will be overinclusive. Providing coverage for contraceptives is cost neutral for an employer or school, 78 Fed. Reg. at 39877, and such coverage is a valuable benefit to some employees and students. Thus, there is no reason that a school or employer that does not object to providing contraception as part of its plan, whether through the accommodation or otherwise, would invoke the exemption, since doing so would deprive its employees or students of a valuable benefit to which it does not object and that does not cost it anything. The line drawn by the agencies, then, is well “within a zone of reasonableness”: It provides relief for those with sincere religious objections to the accommodation without being meaningfully overinclusive.

Any objection to the Rule’s coverage of publicly traded companies similarly lacks merit. There is nothing arbitrary or capricious about including publicly traded entities within the scope of the Religious Exemption Rule. For one thing, RFRA applies to publicly traded entities,

recognizing that they may in some circumstances reflect the religious beliefs of their shareholder. *See Hobby Lobby*, 573 U.S. at 707-08 (discussing the definition of “person” in RFRA). In any case, while Federal Defendants are unaware of any publicly traded entity that developed a sincere religious objection to providing contraceptive coverage, if one were to do so, then it would not be arbitrary and capricious to address that objection. Conversely, if none does, then the mere availability of the exemption harms neither Plaintiffs nor anyone else.

C. The Agencies Adequately Considered The Rules’ Effect on Women.

Plaintiffs make three related allegations regarding the Agencies’ consideration of, and conclusions about, the Rules’ effects on women: (1) the Agencies failed to “consider the Rules’ deleterious effects on the health, economic security, equality, and autonomy of women and others who will lose coverage for contraception”; (2) the Agencies failed to “respond to significant comments” warning of such effects; and (3) the Agencies failed to “provide any reasoned explanation” for abandoning their earlier findings “regarding the benefits of contraception to women’s health and equality.” 2d Am. Compl. ¶ 182(c), (d), (f). All of them are flawed.

First, the Agencies considered the effect of the Rules on women’s health and equality. Indeed, each rule has a section entitled “Health and Equality Effects.” *See* 83 Fed. Reg. 57,555-56 (Religious Rule); 83 Fed. Reg. at 57,611-13. In that section, the Agencies acknowledged that some commenters had contended that the contraceptive mandate “promotes the health and equality of women” and “female participation and equality in the workforce,” 83 Fed. Reg. at 57,555, and “that birth control access generally has led to social and economic equality for women,” *id.* at 57,556. At the same time, however, the Agencies recognized that there are other “policy interests at stake,” such as religious liberty, and that “the best way to balance the various policy interests at stake . . . is to provide the expanded exemptions . . . , even if certain effects may occur among the populations actually affected by the employment of these exemptions.” *Id.* at 57,556. Plaintiffs

undoubtedly disagree with the Agencies' conclusions about the proper balance, but that is precisely the sort of policy question that neither they nor a court may second-guess.

Plaintiffs' argument that the Agencies failed to respond to significant comments is similarly unavailing. An agency's "failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not 'based on a consideration of the relevant factors.'" *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984) (quotation marks omitted)). But here, as explained above, the Agencies explicitly considered comments related to health and equality—they simply balanced those and other policy interests differently from how Plaintiffs would have. As another court concluded, "the Final Rules demonstrate to a commenter that the Agencies considered and rejected the arguments put forth by a commenter, which is all that the APA requires." *Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 812 (E.D. Pa. 2019) (cleaned up).⁴

Finally, the Agencies did not abandon any factual findings about the benefits of contraception on women's health and equality. Rather, as noted above, the Agencies simply concluded that, as a policy matter, the marginal benefits of requiring religious and moral objectors to comply with the *contraceptive coverage mandate*—including any additional benefits related to women's health and equality—did not justify burdening the religious liberty of those with conscience objections to the provision of contraceptive coverage. The Agencies explained that they "view the provision of those protections to preserve religious exercise in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited." 83 Fed. Reg. at 57,556. As

⁴ *Aff'd sub nom. Pennsylvania v. President United States*, 930 F.3d 543 (3d Cir. 2019), as amended (July 18, 2019), *cert. granted sub nom. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 918, 205 L. Ed. 2d 519 (2020), and *cert. granted sub nom. Trump v. Pennsylvania*, 140 S. Ct. 918, 205 L. Ed. 2d 519 (2020), and *rev'd and remanded sub nom. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 207 L. Ed. 2d 819 (2020).

Little Sisters made clear, it was appropriate—indeed necessary—for the Agencies to consider the religious liberty interests affected by the contraceptive coverage mandate, and the balance struck is well within the Agencies’ reasonable discretion. Plaintiffs’ claim therefore fails. *See Nat’l Ass’n of Home Builders*, 682 F.3d at 1038 (holding that “[policy] reevaluation is well within an agency’s discretion.”).

D. The Agencies Had No Need to Consider the “Weight of the Comments.”

Plaintiffs contend that, when issuing the Rules, the Agencies failed to “consider the weight of the hundreds of thousands of comments that were submitted for each of the previous rules relating to the contraceptive coverage requirement, or the post-promulgation comments submitted following the Interim Final Rules.” 2d Am. Compl. ¶ 182(e). This contention lacks merit. First, the APA does not require agencies to consider comments submitted in relation to rules other than the one for which notice has been provided, *see Little Sisters*, 140 S. Ct. at 2386 (listing APA’s notice-and-comment obligations). Nor can such a requirement be grafted on to the APA. *Id.* at 2385. In any event, the Agencies considered comments submitted with respect to prior related rules. *See* 83 Fed. Reg. at 57,539-57,540 (noting that Agencies considered “previously submitted public comments”). Second, the Agencies “responded to post-promulgation comments, explaining their reasons for neither narrowing nor expanding the exemptions beyond what was provided for in the IFRs.” *Little Sisters*, 140 S. Ct. at 2378. The weight of those comments—*i.e.*, the fact that one position received more comments supporting it—is irrelevant. The D.C. Circuit rejected an analogous argument decades ago. *NRDC, Inc. v. EPA*, 822 F.2d 104, 122 n.17 (D.C. Cir. 1987) (“The number and length of comments, without more, is not germane to a court’s substantial-evidence inquiry.”).

E. The Agencies Thoroughly Explained Their Position on the Existence of a Substantial Burden and a Compelling Interest.

Plaintiffs next advance several challenges regarding the burden on religious objectors and the strength of the government’s interest in providing free contraceptive coverage. They contend that the Agencies failed to adequately explain their departures from their prior positions that (i) “the preexisting accommodation does not substantially burden religious exercise”; (ii) “the government has a compelling governmental interest in ensuring that individuals receive coverage of contraception without cost-sharing”; and (iii) “no feasible alternatives are available and that the accommodation is the least restrictive means of furthering the government’s compelling interest in the contraceptive coverage requirement.” 2d Am. Compl. ¶ 182(g)–(i). These arguments are meritless.

Plaintiffs’ fundamental error with respect to all three allegations is ignoring RFRA. As *Little Sisters* recognized, the Agencies “all but” had to consider RFRA in evaluating the religious exemption. 140 S. Ct. at 2383. And under RFRA, the question the Agencies had to address was not whether there is a “compelling governmental interest in ensuring that individuals receive coverage of contraception without cost-sharing.” 2d Am. Compl. ¶ 182(g). Rather, it was whether the accommodation imposes a substantial burden on religious exercise and, if so, whether there is a compelling governmental interest in applying the mandate to the small percentage of employers with sincere religious objections to it. *See Hobby Lobby*, 573 U.S. at 725-26. The Agencies thoroughly explained their reasons for answering *those* questions differently from the prior rule, *see* 78 Fed. Reg. at 39,872-39,873, which is all the APA requires. *See Fox*, 556 U.S. at 515-16.

First, the Agencies explained that their different conclusion regarding the existence of a substantial burden rested on a different view of what the substantial-burden analysis entails. The prior rule had concluded that any burden from the accommodation was insubstantial because “a third party pays for the contraceptive services and there are multiple degrees of separation between

the eligible organization and any individual’s choice to use contraceptive services.” 78 Fed. Reg. at 39,887. In the Religious Exemption Rule, however, the Agencies recognized that “the government cannot second-guess . . . [an] adherent’s assessment of the connection between the government mandate and the underlying religious belief.” 83 Fed. Reg. at 57,546. The Agencies’ current view is correct. As *Little Sisters* explained, *Hobby Lobby* made “it abundantly clear that, under RFRA, the Departments must accept the sincerely held complicity-based objections of religious entities.” 140 S. Ct. at 2383 (internal quotation marks omitted)); see *Hobby Lobby*, 573 U.S. at 723-24. The conclusion that the accommodation substantially burdens religious exercise followed from the Agencies’ new—and correct—legal understanding. Because various entities contended that complying with either the Mandate or the accommodation was inconsistent with their sincere religious beliefs, the Agencies concluded that “withholding an exemption from those entities has imposed a substantial burden on their exercise of religion.” 83 Fed. Reg. at 57,546.

Second, the Agencies offered multiple reasons why applying the mandate *to objecting entities* does not serve a compelling governmental interest:

(1) Congress did not mandate coverage of contraceptives. 83 Fed. Reg. at 57,546-47.

(2) Even without the religious exemption, many other health plans are not required to provide contraceptive coverage, including grandfathered plans, exempt churches and their integrated auxiliaries, and self-insured church plans that availed themselves of the accommodation. *Id.* at 57,547; cf. *Advocate Health Care Network*, 137 S. Ct. 1652, 1658-59 (2017).

(3) In the Agencies’ expert view, the administrative record did not contain adequate evidence to meet the high standard of demonstrating a compelling interest, 83 Fed. Reg. at 57,547.

(4) Some objecting entities are willing to cover some (even if not all) contraceptives, and contraceptives are available from alternative sources, including from government programs for low-income women. *Id.* at 57,548. This is particularly relevant given research analyzing the effect

of ACA implementation on contraceptive use, which concluded that: “[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear.” M.L. Kavanaugh et al., *Contraceptive Method Use in the United States: Trends and Characteristics Between 2008, 2012 and 2014*, 97 *Contraception* 14, 14–21 (2018), AR at 00804231, attached as Ex. A (cited at 83 Fed. Reg. 57,548).

In addition, although the Agencies had previously sought to provide contraceptive coverage to women “seamlessly,” the Agencies determined that the government did not have a compelling interest in such seamlessness because even the prior rule created multiple exceptions to it, including exemptions for grandfathered plans, churches, and churches’ integrated auxiliaries, as well as the application of the accommodation to self-insured church plans. 83 Fed. Reg. 57,548.

These considerations are more than sufficient to support the Agencies’ conclusion that the mandate does not further a compelling government interest as applied to employers with religious objections, notwithstanding any prior contrary conclusion. Although the existence of exceptions is by no means dispositive, “a law cannot be regarded as protecting an interest of the highest order . . . when it leaves appreciable damage to that supposedly vital interest unprohibited.” *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 547 (1993) (cleaned up).

Relatedly, Plaintiffs’ allege that the Agencies inadequately explained their change in position with respect to the existence of “feasible alternatives” and whether “accommodation is the least restrictive means of furthering the government’s compelling interest in the contraceptive coverage requirement.” 2d Am. Compl. ¶ 182(i). Not so. These allegations highlight previous agency determinations that presupposed a compelling interest in applying the mandate to objecting entities to provide cost-free contraceptive coverage. But as established above, the Agencies have reasonably concluded that there is no such interest. As the “[a]genc[ies]’ path” in moving away from these earlier determinations “may reasonably be discerned,” *Bowman Transp., Inc. v.*

Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 286 (1974), they did not violate the arbitrary and capricious clause.

F. The Agencies Appropriately Considered Any Reliance Interests.

Plaintiffs insist that the Agencies failed to “consider the serious reliance interests of Plaintiffs and countless others on the contraceptive coverage requirement and preexisting accommodation process.” 2d Am. Compl. ¶ 182(j). This allegation is incorrect. Because RFRA requires the religious exemption, *see* § H below, the Agencies were not required to consider reliance interests, as they would if the decision were a matter of discretion. In any case, the Agencies in fact considered whether the contraceptive coverage mandate has “led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive, contraceptive methods.” *See, e.g.*, 83 Fed. Reg. at 57,556. These are obvious indicia of reliance on contraceptive coverage; the extent to which the mandate has “led” women to change (or not change) their behavior indicates the extent to which they have relied on the mandate. And while the Agencies ultimately concluded that they did not need to reach a conclusion on these issues, given the limited scope of the Rules and strength of the religious liberty interests at stake, they were not blind to them. *See, e.g.*, 83 Fed. Reg. at 57,556.

G. The Agencies’ Regulatory Impact Analysis Is Not Arbitrary or Capricious.

Plaintiffs further allege that the Agencies’ decision was arbitrary and capricious because the Regulatory Impact Analysis (RIA) “disregard[ed] significant direct and indirect costs identified by commenters,” in supposed violation of Executive Order 12,866 and internal government guidelines. 2d Am. Compl. ¶ 111 (citing Office of Management and Budget (OMB) Circular A-4 (2003), and HHS Guidelines for Regulatory Impact Analysis (2016)). This claim should fail, both

because it is not reviewable and because the record demonstrates that the RIA was reasonable and consistent with Executive Branch requirements.

As an initial matter, Plaintiffs' claim that the RIA violates Executive Order 12,866 is not reviewable. "An Executive Order devoted solely to the internal management of the executive branch—and one which does not create any private rights—is not . . . subject to judicial review." *Meyer v. Bush*, 981 F.2d 1288, 1296 n.8 (D.C. Cir. 1993). Executive Order 12,866 explicitly states that it is "intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law." *See also Air Transport Ass'n of Am. v. FAA*, 169 F.3d 1, 8 (D.C. Cir. 1999) (finding that such explicit disclaimers preclude judicial review of an arbitrary and capricious challenge to cost-benefit analyses). Thus, "Executive Order 12,866 does not create judicially enforceable rights, nor does it provide a basis for rejecting final agency action." *Nat'l Truck Equip. Ass'n v. Nat'l Highway Traffic Safety Admin.*, 711 F.3d 662, 670 (6th Cir. 2013).⁵

For similar reasons, Plaintiffs' reliance on internal OMB and HHS guidance documents is misplaced. Private parties cannot enforce internal agency rules intended solely to benefit the agency. *See Lopez v. FAA*, 318 F.3d 242, 247 (D.C. Cir. 2003). Neither OMB Circular A-4 nor the HHS Guidelines for Regulatory Impact Analysis create any substantive rights for third parties that may be enforced against the agencies. The OMB guidance makes clear that it serves only to "provide[] the [OMB]'s guidance to Federal agencies on the development of regulatory analysis as required under . . . Executive Order 12866." OMB Circular A-4 (2003), https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/; *see also Am. Fed'n of Gov't Employees*,

⁵ *Accord Teledyne, Inc. v. United States*, 50 Fed. Cl. 155, 190 (2001), *aff'd sub nom. Allegheny Teledyne Inc. v. United States*, 316 F.3d 1366 (Fed. Cir. 2003); *All. for Nat. Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 135 n.10 (D.D.C. 2011).

AFL-CIO, Local 1367 v. United States, No. CIV.A. SA00CA1508 HG, 2001 WL 262897, at *7 (W.D. Tex. Mar. 7, 2001) (an OMB Circular “cannot create enforceable rights in third parties ‘because the executive branch, including OMB, simply has no power to make the law; the power rests exclusively with Congress.’”). Similarly, the HHS Guidelines serve to “assist [HHS]’s agencies” in “strengthening regulatory analysis”—they, too, create no enforceable legal rights for third parties. Dep’t of Health and Human Servs., Guidelines for Regulatory Impact Analysis 2016 at 1, https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf (HHS Guidance).

Even if this Court were to determine that it may review the RIA’s adherence to the Executive Order or internal guidance, however, its review of such cost-benefit analyses should be particularly deferential. The principle “that a court is not to substitute its judgment for that of the agency” is “especially true when the agency is called upon to weigh the costs and benefits of alternative policies.” *Consumer Elecs. Ass’n v. FCC*, 347 F.3d 291, 303 (D.C. Cir. 2003) (quoting *State Farm*, 463 U.S. at 43 & *Ctr. for Auto Safety v. Peck*, 751 F.2d 1336, 1342 (D.C. Cir. 1985)). Accordingly, when reviewing a challenge to an agency’s cost-benefit analysis, a court limits its role to determining whether “the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Ctr. for Auto Safety*, 751 F.2d at 1342.

The RIA is plainly reasonable and contains no “clear errors of judgment.” *See* 83 Fed. Reg. at 57,573-81. The Executive Order and Guidance make clear that RIAs must only quantify costs and benefits “to the fullest extent that these can be usefully estimated.” EO 12,866 § 1(a); Circular A-4; HHS Guidance at 43. And the Rules make clear that the kinds of costs that Plaintiffs claim should have been included—such as harm to “economic security, equality, and autonomy”—are the kinds that could not be usefully estimated. *See* 83 Fed. Reg. at 57,544 (“[I]t is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general.”) *see also id.*

at 57,548 (“Some commenters attempted to quantify the costs of unintended pregnancy, but failed to persuasively estimate the population of women that this exemption may affect.”).

Plaintiffs also wrongly claim that the RIA improperly “disregards significant direct and indirect costs identified by commenters.” 2d Am. Compl. ¶ 111. In fact, the Agencies made clear that they *did* consider such comments, but that the comments “d[id] not . . . substantially assist [them] in estimating how many women would be affected.” 83 Fed. Reg. 57,574-75. Instead, the Agencies engaged in an exhaustive analysis to estimate the number of women who may experience increased contraceptive costs based on calculations of the number of prior litigating entities, as well as user-fee reductions, ultimately concluding that the Final Rules may increase contraceptive costs for approximately 70,500 women, with a total financial transfer effect of \$41.2 million per year. *See id.* at 57,577-78. The Agencies recognized that some commenters suggested that this estimate was too low, but found that such commenters “did not support their proposed higher numbers with citations or specific data that could be verified as more reliable” than the Agencies’ estimates. *Id.* at 57,578. Although the Agencies’ estimates were uncertain because of the limited data available, *id.* at 57,577, given the limited data available, their reasoning is clear and reasonable, which is all the APA requires, even where cost-benefit analyses are reviewable. Therefore, even if the challenge to the RIA were reviewable, the RIA comports with the APA.

H. The Majority of Plaintiffs’ Arguments with Respect to the Religious Exemption Rule Fail Under the Harmless Error Provision of the APA.

As noted above, the majority of Plaintiffs’ allegations under the arbitrary and capricious clause assail the Rules for inadequately considering or explaining certain issues. *See* 2d Am. Compl. ¶¶ 182(c)-(k). These allegations lack merit. *See* § C-F above. But even if they were meritorious, they would fail with respect to the Religious Exemption Rule under the APA’s harmless error clause. Under that clause, “due account shall be taken of the rule of prejudicial error.” 5 U.S.C. § 706. Any error here would be harmless. The arbitrary and capricious clause

exists to ensure that agencies engage in reasoned decisionmaking. *E.g.*, *Fox v. Clinton*, 684 F.3d 67, 74-75 (D.C. Cir. 2012). But the agencies had no decision to make with regard to the Religious Exemption Rule: RFRA obligated the Agencies to issue it. To be sure, the Agencies nevertheless considered all the factors Plaintiffs identify and thoroughly explained that they would have issued the same Rule even if the matter were a discretionary one. But because RFRA required the religious exemption, it ultimately does not matter what the Agencies considered or did not consider, or how they explained their decisionmaking process.

The Religious Exemption Rule was required by RFRA, which prohibits the government from “substantially burden[ing] a person’s exercise of religion” unless the government “demonstrates that” application of the burden to that person is “the least restrictive means” of furthering a “compelling governmental interest.” 42 U.S.C. § 2000bb-1(b). The accommodation does not eliminate the substantial burden that the contraceptive-coverage mandate imposes on certain employers with conscientious objections. As became clear in litigation following *Hobby Lobby*, some employers hold the sincere religious belief that participating in a process by which their employees receive contraceptive coverage “makes them complicit in providing [that] coverage,” even if the coverage is actually paid for by other parties. *Priests for Life v. HHS*, 808 F.3d 1, 15 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from denial of rehearing en banc). Those employers believe that the accommodation is such a process because it commandeers their own health plans to provide coverage, and requires them to facilitate notification to the health plan issuer or third-party administrator that will, upon receiving such notification, provide contraceptive coverage in connection with their plans. *See id.* at 25 n.11; *see also Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927, 939-43 (8th Cir. 2015), *vacated and remanded*, 136 S. Ct. 2006 (2016); 83 Fed. Reg. at 57,546. Offering the accommodation as an alternative means of compliance with the mandate thus leaves in place the same “substantial burden on the ability of the objecting parties to

conduct business in accordance with their religious beliefs” that this Court identified in *Hobby Lobby*. 573 U.S. at 720, 724 (emphasis omitted). If the objecting employers “d[id] not yield to th[e] demand” to violate their beliefs, the “economic consequences” would be every bit as “severe.” *Id.* at 720. Indeed, the very same \$100-per-day-per-employee tax, or \$2,000-per-year-per-employee penalty, would apply. *See id.*; 26 U.S.C. §§ 4980D, 4980H; *see also Priests for Life*, 808 F.3d at 19 (Kavanaugh, J., dissenting) (concluding that the accommodation imposes a substantial burden on RFRA plaintiffs “under *Hobby Lobby*”).

Because requiring religious objectors to comply with the mandate through the accommodation would impose a “substantial burden” on their religious exercise, the agencies could only demand such compliance if they “demonstrate[] that application of the” accommodation “is the least restrictive means of furthering [a] compelling governmental interest.” 42 U.S.C. 2000bb-1(b). The agencies have now recognized that they cannot make that showing, as discussed above. *See* 83 Fed. Reg. at 57,546-57,548; *see also* § E above. Under RFRA, therefore, the agencies were required to provide an exemption for religious objectors.

In assessing whether an asserted governmental interest is compelling, the Supreme Court has explained that “a law cannot be regarded as protecting an interest of the highest order . . . when it leaves appreciable damage to that supposedly vital interest unprohibited.” *Church of Lukumi Babalu Aye*, 508 U.S. at 547 (citation omitted). Thus, in *Gonzales v. O’Centro Espirita Beneficiente Uniao do Vegetal*, the Supreme Court held that the existence of an exemption from requirements of the Controlled Substances Act for individuals who use peyote for religious purposes undermined the position that denying a similar exemption to those who use hoasca for such purposes was necessary to advance a compelling governmental interest. 546 U.S. 418, 433 (2006). Here, that same principle strongly supports the Agencies’ conclusion. Neither the contraceptive-coverage mandate itself nor the accommodation has ever been applied to the tens of

thousands of employers that qualify as “churches, their integrated auxiliaries, and conventions or associations of churches,” 26 U.S.C. § 6033(a)(3)(A)(i); *see* 76 Fed. Reg. at 46,623; 83 Fed. Reg. at 57,580. And since 2013, coverage for employees insured through self-insured “church plans” of church-affiliated not-for-profit organizations—including a number of large religious universities and hospitals—has been effectively voluntary as well. *See* 79 Fed. Reg. at 51,095 n.8. Especially given those longstanding exemptions, the agencies correctly determined that they could not claim that applying the mandate or accommodation to other religious objectors was necessary to satisfy a compelling governmental interest. *See* 83 Fed. Reg. at 57,546-48.

The Agencies also correctly recognized that any interest in “seamless” contraceptive coverage is not compelling. Women who participate in health plans maintained by objecting organizations can often obtain contraception (if they want it) through other means, including existing federal, state, and local programs that provide free or subsidized contraceptives to low-income women. *See* 83 Fed. Reg. at 57,548. And although utilizing the health plans of objecting employers to provide access to contraception might make such access marginally more convenient, that additional convenience is not the sort of “paramount interest[]” that has been recognized as compelling. *Sherbert v. Verner*, 374 U.S. 398, 406 (1963) (citation omitted).

This Court previously disagreed with the conclusion that RFRA required the Agencies to issue the Religious Exemption Rule. *Irish 4 Reprod. Health*, 434 F. Supp. 3d at 707-08. But the Court should reverse its conclusion in light of *Little Sisters*. This Court declined to find a substantial burden, explaining that the accommodation does “*not* compel Notre Dame to change its own actions and speech in a manner contrary to its sincerely held religious beliefs, but instead merely requires the University to state its objections to contraception coverage.” *Id.* (cleaned up). Next, the Court rejected the argument that participating in the accommodation makes Notre Dame a “conduit” for birth control, citing the Third Circuit’s analysis in the *Little Sister’s* case. *Id.* But

the Supreme Court’s decision in *Little Sisters* undermines these conclusions, emphasizing that it is “abundantly clear that, under RFRA, the [Agencies] must accept the sincerely held complicity-based objections of religious entities.” 140 S. Ct. at 2383 (citing *Hobby Lobby*, 573 U.S. at 723-24). Justice Alito’s concurrence in *Little Sisters* explains in greater detail why a contrary conclusion as to the existence of a substantial burden is warranted. Justice Alito explained that “[i]t is undisputed that the Little Sisters have a sincere religious objection to the use of contraceptives and that they also have a sincere religious belief that utilizing the accommodation would make them complicit in this conduct. As in *Hobby Lobby*, it is not for us to say that their religious beliefs are mistaken or insubstantial.” *Little Sisters*, 140 S. Ct. 2390. He reiterated the point later in his opinion, explaining why the Third Circuit’s conclusion, which was cited by this Court, was incorrect: “The inescapable bottom line is that the accommodation demanded that parties like the Little Sisters engage in conduct that was a necessary cause of the ultimate conduct to which they had strong religious objections Where to draw the line in a chain of causation that leads to objectionable conduct is a difficult moral question, and our cases have made it clear that courts cannot override the sincere religious beliefs of an objecting party on that question.” *Id.* at 2391. This Court should reach the same conclusion here. And in view of the absence of a compelling interest, *see id.* at 2392-31, § E above, the Court should hold that RFRA required the Agencies to issue the Religious Exemption Rule. In sum, because RFRA required the Religious Exemption Rule, the alleged shortcomings in the Agencies’ decisionmaking process that Plaintiffs’ assail in ¶¶ 182(c)-(k) of the Second Amended Complaint constitute harmless error.

CONCLUSION

For the foregoing reasons, the Court should grant Federal Defendants summary judgment on Count III of the Second Amended Complaint to the extent that it alleges an arbitrary-and-capricious claim.

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Respectfully submitted,

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